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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/289,000	02/25/1997	GERALD BLATT	16683-1-2	8112

7590 01/14/2003

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EXAMINER

PREBILIC, PAUL B

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 01/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.



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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Paper No. 35

Application Number: 09/289,000  
Filing Date: February 25, 1997  
Appellant(s): BLATT, GERALD

\_\_\_\_\_  
J. Georg Seka  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed November 4, 2002.

**(1) *Real Party in Interest***

A statement identifying the real party in interest is contained in the brief.

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**(2) Related Appeals and Interferences**

A statement identifying the related appeals and interferences, which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

**(3) Status of Claims**

The statement of the status of the claims contained in the brief is correct.

**(4) Status of Amendments After Final**

The Appellant's statement of the status of amendments after final rejection contained in the brief is correct. The amendment after final was entered and all but the prior art rejection have been withdrawn.

**(5) Summary of Invention**

The summary of invention contained in the brief is correct.

**(6) Issues**

The Appellant's statement of the issues in the brief is correct.

**(7) Grouping of Claims**

Appellant states that all the claims stand or fall together.

**(8) Claims Appealed**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(9) Prior Art of Record**

5,207,712	Cohen	05-1993
5,007,939	Delcommune et al	04-1991

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**(10) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

***Claim Rejections Based Upon Prior Art***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4-6, 8-10, and 24-31 are rejected under 35 U.S.C. 102(b) as anticipated by Cohen (US 5,207,712) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cohen (US 5,207,712) alone. Cohen (US 5,207,712) anticipates the claim language wherein the resection of bone ends or the holes drilled into the bone ends expose the cancellous bone surface and the solid sphere and rods allowing both for joint flexion and extension after implantation (see Col. 4, lines 38 and 39). The ball (4) provides a sliding surface for the joint ends; see the whole document, especially Col. 3, lines 18-20; Col. 4, lines 3-39 and Figures 1-3 and 8-11. In particular, Figure 10 demonstrates how the joint section (61) is removed on both bone ends to expose the underlying cancellous bone surfaces. The face as claimed is in the outside of ball (4),

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and it is exposed to cancellous surfaces on both sides of the joint where it provides a 1.3 to 1.5 mm gap therebetween; see Figure 1, column 2, lines 37-44 and column 3, lines 18-20.

Alternatively, one could view the ball (4) as not providing a sliding surface because it is not explicitly stated as providing such. However, the Examiner posits that one viewing this embodiment would be led to the conclusion that the ball (4) obviously functions as a stop and sliding surface for the resected bone ends because the joint flexes and extends around the ball surface; see column 4, lines 38-39.

With regard to claims 8 and 9, Applicant is directed to Figure 1 and especially Figure 2 for claim 8. It is noted that the first and second face of Cohen is on opposed sides of the spacer such that it reads on the claim language.

With regard to claim 24 specifically, the Examiner posits that a period of 6 to 7 months would be sufficient to allow all the natural processes of the permitting step as claimed to take place; see Col. 2, lines 45-48.

With regard to claims 4, 10, and 25 specifically, the estimating step as claimed is inherently or implicitly present in Cohen who makes his device for a particular joint type so that as much regrowth between the joints can take place.

Claims 2 and 3 are rejected under 35 U.S.C. 103 as being unpatentable over Cohen (US 5,207,712) in view of Delcommune et al (US 5,007,939). Cohen meets the claim language except for the use of lactic acid polymer or copolymer as claimed. Delcommune et al, however, teaches that it has been known to use lactic acid polymer or copolymer for resorbable bone repair devices. Hence, it is the Examiner's position

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that it would have been obvious to one of ordinary skill in the art to use lactic acid polymer or copolymer in place of or in addition to the polymer of Cohen for the same reasons that Delcommune et al uses the same and in order to further reduce the cost of making the device.

**(11) Response to Argument**

**ISSUE 1**

In reviewing the arguments presented by the Appellant, it was concluded that many unsubstantiated assumptions were made about Cohen by Appellant. In particular, Appellant argues that Cohen's rod and ball are rigid, but Cohen explicitly states nothing about the flexibility of the implant. Rather, Cohen clearly implies that the implant material is flexible because it was chosen to avoid the rigidity and foreign body reactions of polyglycolic acid materials; see column 1, lines 43-52.

Furthermore, Cohen states that the joint can be flexed and extended such that dislocation of the implant should not occur; see column 4, lines 37-39. Therefore, since the implant has a rod extending into the bone on either side of the joint, it is reasonable to conclude that the rod must bend in order that the flexion and extension motion is provided.

Appellant also argues that flexion of the joint after implantation would result in sheering of the rod from the ball of Cohen. However, this argument is unpersuasive because Cohen states that flexion should not result in dislocation of the implant; see column 4, lines 37-39. Furthermore, contrary to the manner depicted by Appellant's

Figures A1, A2, and A3, "a tight fit between the holes and implant shafts is not required." This suggests that Cohen teaches away from a tight fit such that Figures A1, A2, and A3 are not fair depictions of Cohen's method.

Moreover, since the fit of the holes and rod of shaft of Cohen are not tight like Chemow, et al, the Examiner posits that at least some slight motion is possible to the extent required by the present claim language. The Board is directed to note that no degree or type of sliding is set forth such that even slight flexion-extension motion, lateral motion, or swivel motion would be provided such that sliding would necessarily take place. Therefore, contrary to the Appellant's assertion, not only is sliding possible in Cohen, but it is necessary because of the flexion-extension motion and because of the loose fitting rod.

## **ISSUE 2**

In traversing the Section 103 rejection, Appellant argues that Cohen cannot provide slidable motion because sliding motion would require sheering off the rod from the ball. However, this assumes that Cohen's material is rigid and cannot be flexed at the joint. Furthermore, flexion-extension motion is only one type of possible motion available in a joint. Joint can also be moved laterally and in a swivel direction. For this reason, this argument is not commensurate with the scope of the present claim language.

As to the Rule 132 declarations, the Examiner found them insufficient because they failed to objective show that Cohen's device would not function as stated therein or

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that the material was too inflexible to bend without breaking. In particular, the declarations lack objective evidence to support the Appellant's assertions.

The declaration under 37 CFR 1.132 filed November 27, 2001 by Gerald Blatt is insufficient to overcome the rejection of claims 1-6, 8-10, and 24-31 based upon Cohen as set forth in the last Office action because:

In response to the traversal that sliding motion would not be possible with the Cohen device and bone joint fusion would result, the Examiner posits that this argument directly contradicts Cohen which states that knitting of the bone ends is prevented by the gap provided; see the abstract and column 4, lines 37-39. In addition, fibrous growth is only present after some time post-implantation so sliding motion is at least still present initially.

The Blatt declaration provides no objective evidence of unobviousness. Rather, arguments are provided to explain why Blatt, the present inventor, believes that Cohen would result in a fused joint. For this reason, the probative value of such a declaration is less than that of a declaration providing objective evidence.

The following is an excerpt from MPEP 716.01(c):

**"To be of probative value, any objective evidence should be supported by actual proof. Objective evidence which must be factually supported by an appropriate affidavit or declaration to be of probative value includes evidence of unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. See, for example, *In re De Blauwe*, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984) ("It is well settled that unexpected results must be established by factual evidence." "[A]ppellants have**



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**not presented any experimental data showing that prior heat-shrinkable articles split. Due to the absence of tests comparing appellant's heat shrinkable articles with those of the closest prior art, we conclude that appellant's assertions of unexpected results constitute mere argument." See also *In re Lindner*, 457 F.2d 506, 508, 173 USPQ 356, 358 (CCPA 1972); *Ex parte George*, 21 USPQ2d 1058 (Bd. Pat. App. & Inter. 1991)."**

**"In assessing the probative value of an expert opinion, the examiner must consider the nature of the matter sought to be established, the strength of any opposing evidence, the interest of the expert in the outcome of the case, and the presence or absence of factual support for the expert's opinion. *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281, 227 USPQ 657 (Fed. Cir. 1985)." (emphasis added by Examiner)**

It is noted that the declaration contains no clear nexus to the claimed invention that does not require that the sliding motion is provided after the healing takes place. For this reason, the declaration fails to be clearly relevant to the claimed invention.

The declaration under 37 CFR 1.132 filed November 27, 2001 by Ronald Smith is insufficient to overcome the rejection of claims 1-6, 8-10, and 24-31 based upon Cohen as set forth in the last Office action because:

There is no objective evidence or actual proof to support declarant's allegations and arguments.

Smith argues that Cohen is for a foot or weight bearing joint, but the present invention is directed to hand or non-weight bearing joints. However, upon reviewing the claims of record, it is clear that they are drawn to the treatment of a joint irrespective of location in the body and they do not preclude use in a foot.

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The declarant next points out that he is familiar with the silicone implants mentioned in the Cohen background. The Examiner posits that silicone implants are not relevant to the Cohen invention, which uses an absorbable material. Furthermore, even if the silicone implants were considered relevant to the Cohen biodegradable implant, the declaration is insufficient in this regard because declarant states that the silicone implants "permit essentially no motion." This suggests that some motion is provided or at least this statement is vague in this regard. Additionally, declarant states that "some bending of the continuous fibrous tissue body, which can take place when sufficient force is applied." Again, this suggests that some motion is provided and the only difference between Cohen's device and the present device is a matter of degree of motion. For this reason, this line of argument is considered unpersuasive.

Subsequently, Smith states that ORTHOSORB absorbable pins, if implanted in a joint, would immobilize it. Again, Cohen mentions absorbable pins in the background of the disclosure, and thus, it is not relevant to Cohen's device as disclosed.

Next, declarant argues that Cohen "does not provide mobility to the toe joint." In response, the Examiner posits that this statement is speculative because the Cohen device was never tested. Furthermore, declarant even states that some motion is provided by fibrous tissue; see the second full paragraph of page 3 of the declaration.

Declarant concludes that Cohen does not provide an articulating joint. The Examiner posits that some joint motion is admitted by declarant and the rest is a matter of relative degree. Since the claims do not specify the degree of motion provided, the argument is not considered relevant to the claimed invention.

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Finally, since the Smith declaration provides some evidence that motion does occur when fibrous tissue grows between bone ends of a toe joint, this evidence becomes a teaching of obviousness rather than unobviousness. For this reason, the Examiner posits that claimed invention is considered at least clearly obvious over Cohen.

### **ISSUE 3**

As to the rejection of claims 2 and 3 by Cohen and Delcommune, the Examiner notes that Appellant relies solely on their traversal of claim 1 to show unobviousness. However, since claim 1 is considered unpatentable, claims 2 and 3 should stand or fall therewith.

For the above reasons, it is believed that the rejections should be sustained.

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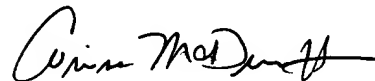
Respectfully submitted,

pbp  
January 7, 2003



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